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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,457	12/17/2003	Hendrik-Jan Houthoff	570-29 PCT/US/CON	9335
23869	7590	04/07/2005	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICO TURNPIKE SYOSSET, NY 11791			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER

1645

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/739,457

Applicant(s)

HOUTHOFF ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicants' Response to Office Action, received 11 January 2005, is acknowledged.

Claims 3-5 and 8-14 have been amended.

It is noted that claim 1 is listed as "Original". However, the claim has been improperly amended. Line 2 now reads "the steps of" whereas the original claim 1 recites "the steps of" and line 3 now reads "a) contracting" whereas original claim 1 recites "a) contacting".

2. Claims 1-16 are pending and under consideration.

### Rejections maintained

3. The rejection of claims 1-16 under 35 U.S.C. 112, second paragraph, indefiniteness for merely detecting Ag-Ab complexes, is maintained for reasons of record.

Applicants argue that the instant claims do not require that whole *Mycobacterium* per se be detected, only identified. Similarly, the claims are not directed to detecting a whole *Mycobacterium* by adding both the antigen and antibody to a sample, but to detecting immune complexes which permit the identification of the *Mycobacterium* which is or was present in the individual being tested.

The examiner has considered applicants' arguments, and finds it partly persuasive concerning the detection of whole *Mycobacterium*. However, the examiner does not find it persuasive concerning identifying a species of *Mycobacterium* if one adds both  $\geq 1$  ImCRAC and  $\geq 1$  antibody which already binds to the ImCRAC. In this embodiment of the claims, the only thing one is identifying is a binding reaction between the added exogenous antibody and ImCRAC.

4. The rejection of claims 1-16 under 35 U.S.C. 112, first paragraph, scope of enablement for all/other species of *Mycobacteria*, is maintained for reasons of record.

Art Unit: 1645

Applicants argue that the claims are not directed to particular set or group of *Mycobacterial* species or their particular ImCRACs that are characteristic of a *Mycobacterial* species, but consistent with the ImCRAC technology, can identify and monitor infections due to a range of *Mycobacterial* species.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection. The instant claims are drawn to a method for identifying any mycobacterial species comprising (a) contacting  $\geq 1$  ImCRAC of a mycobacterial species with a body fluid sample, (b) contacting  $\geq 1$  antibody which is capable of reacting with a mycobacterial antigen, with said body fluid sample; and c detecting the presence of antigen-antibody complexes, and identifying the *Mycobacterium* species present in said body fluid sample.

As stated in the original rejection, the instant specification only teaches that *M. tuberculosis* is identified when one uses *M. tuberculosis* crude extract and antibodies raised against *M. tuberculosis*. The specification does not provide sufficient guidance concerning how to identify one species of *Mycobacterium* by utilizing  $\geq 1$  ImCRAC from another different species of *Mycobacterium* and utilizing  $\geq 1$  antibody capable of reacting with yet another mycobacterial antigen.

5. The rejection of claims 1-16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Pat. No. 6,733,983, is maintained.

Applicants argue that they are obtaining a Terminal Disclaimer from the owner of the instant application.

Art Unit: 1645

The examiner has considered applicants argument and the rejection will be maintained until a Terminal Disclaimer has been received.

### **Conclusion**

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

Art Unit 1645

March 29, 2005